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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,739	11/13/2003	Petar R. Dvornic	MIC35 P-334	8890

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,739

Applicant(s)

DVORNIC ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

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1) In claim 14, line two, should "N-hydroxysuccidimyl" be "N-hydroxysuccinimidyl"?

2) Although specific claims are cited in the rejections set forth below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) The claims are rejected as being based on a specification which does contain a description of the term "polymer network". Paragraphs [0015] and [0045] of the specification refer to "networks" but provide no definitive description of the term.

b) The claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "compounds" wherein lipid chains are present {specification: paragraphs [0035], [0039], [0043] and [0044]}, does not reasonably provide enablement for "compounds" which do not contain lipid chains. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the invention commensurate in scope with these claims. Without the presence of such lipid components, it is not clear that the "compounds" would function for the intended purpose of the invention.

c) Claims 1 and 10-30 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for the preparation of a "compound" wherein acetylenic group-containing components attached to each "dendritic polymer" are intermolecularly polymerized after their attachment to the individual "dendritic polymers", does not reasonably provide enablement for the case wherein the "interdendritic cross-linking" occurs prior to the attachment of the segments containing acetylenic moieties to the "dendritic polymers". The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with the claims.

6) Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) It is unclear what is meant by the term "network" since the required structure is undefined thus rendering the claims indefinite.

b) In claim 1, it is unclear what is meant by the term "cross-linking segments of alternating conjugated double and triple bonds". It is noted that this terminology would include the presence of aromatic rings for which there is no enabling written disclosure in the specification.

c) Claim 1 recites "a dendritic polymer network compound" but requires no dendritic polymer as a component; the only requirement for the "compound" is that it be comprised of "at least one sensory group" and "interdendritic cross-linking segments". It is also unclear where and how the "sensory group" is attached to the rest of the "compound". The exact structures meant to be included by claims 1 and 13 cannot be determined.

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d) For claims 10-12, there is no antecedent basis in claim 1 for the term "a dendritic segment".

e) Claims 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a requirement for specific binding between the analyte and its corresponding binding partner, a step in which such binding is indicated by a detectable change which is monitored and step whereby the detectable change is correlated with the amount/presence of analyte in the sample.

f) For claim 25, there is no antecedent basis in claim 1 for the term "a chemical and/or biological sensing material".

g) For claim 13, it is unclear exactly what is meant to be included by the term "a group that is less reactive than X".

7) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8) Claims 13-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9-29 of copending Application No. 10/068,378. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a "compound" comprised of a "dendritic polymer core" to which a "diacetylene reagent" is attached. The "compounds" of claim 13 of S.N. 10/712,739 include

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the compounds of claim 1 of S.N. 10/068,378 which have "segments containing alternating conjugated double and triple bonds formed by intramolecular linking of diacetylene moieties bonded to the dendritic polymer core".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11) Claims 13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Lee et al (Polymer Preprints (2002), 32(2), p. 450), Sui et al (Colloids and Surfaces A: Physicochemical and Engineering Aspects 171 (2000), pp. 185-197) or Balogh et al (Macromolecules (1999), 32, pp. 1036-1042).

Each of the references describes a diacetylene functionalized dendritic compound obtained by reaction of a dendritic polymer with a diacetylene reagent which anticipates the compounds of instant claims 13, 15 and 16. See Lee et al: "Experimental"; Sui et al: page 186, the first full paragraph of the second column; Balogh et al: "Experimental Section", "Synthesis". It is noted that the compounds of

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instant claims 13-16 do not require the presence of any "interdendritic cross-linking segments of alternating conjugated double and triple bonds" as required for the compounds of instant claim 1.

12) Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over each of Lee et al (Polymer Preprints (2002), 32(2), p. 450), Sui et al (Colloids and Surfaces A: Physicochemical and Engineering Aspects 171 (2000), pp. 185-197) or Balogh et al (Macromolecules (1999), 32, pp. 1036-1042).

The cited references are applied for the reason stated in the paragraph directly above. For instant claim 14, the specific reactive functional groups "X" constitute obvious choices from among well known equivalent reactive functional groups, the particular functional group not having been described as critical to the practice of the invention. For example, for the N-hydroxysuccinimidyl ester functional group of claim 14, see Sui et al, page 187, 2.2 *Synthesis*, which uses a reagent containing a succinimidyl ester functional group.

13) Claims 1-12 and 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sui et al (Colloids and Surfaces A: Physicochemical and Engineering Aspects 171, pp. 185-197 (2000)).

Sui et al describe a dendritic polymer to which a diacetylenic compound (10,12-pentacosadiynoic acid) is attached and in which the diacetylenic linkages are then further polymerized to form intermolecular alternating conjugated double and triple bonds; this composition is UV detectable. See Sui et al: page 186, the first full paragraph of the second column; page 196, wherein "the observed polymerization must extend from one dendrimer to another dendrimer". These are the same type of dendritic polymer-diacetylene conjugates described in instant claim 1. Although Sui et al do not specifically address the presence of any terminal biomolecules on their dendritic polymer-diacetylene conjugates, they establish that it is well known in the art to attach biomolecules to this type of conjugate "for their potential applications in molecular recognition, ...chemical sensors". See Sui et al: the first paragraph of the Introduction. Given the Sui et al description of the state of the art, it would be obvious

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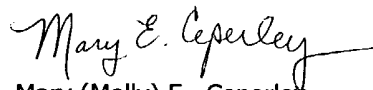
to modify the Sui et al conjugates to contain a terminal biomolecule moiety, as claimed, with the expectation of obtaining a useful UV detectable biosensor. The features of the dependent claims are either specifically described by the references (e.g. for the "dendrimer" of claim 2, see the abstract of Sui et al) or constitute obvious variations in parameters which are routinely modified in the art (e.g. extent of branching of the dendrimer of instant claim 5; choice of one of equivalent types of reactive functional groups as in instant claims 17-20) and which have not been described as critical to the practice of the invention. Since the biomolecule sensor conjugates of the instant claims are obvious from the description of Sui et al as described above, the use of these same biosensor conjugates in a conventional biosensing method (instant claims 25-30) would be likewise be obvious.

14) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 21, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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